

IFW

Docket No. MCP0295DIV

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Harry S. Sowden, et al.

Serial No. : 10/782,551

Art Unit: 1615

Filed : February 19, 2004

Examiner: Not Yet Assigned

For : SYSTEMS, METHODS AND APPARATUSES FOR MANUFACTURING  
DOSAGE FORMS

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June 3, 2004

(Date of Deposit)

David R. Crichton

(Name of applicant, assignee, or Registered Representative)



(Signature)

June 3, 2004

(Date of Signature)

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P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e)  
(attached); or

☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with \$1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in \$1.17(p).

☐ In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with \$1.97(e) as set forth below and the fee of \$180.00 as set forth in \$1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.


☐ The relevance of those listed references which are not in the English language is as follows: For German Patent No. DE7535875, Title: Mechanism for the filling of a press for squeezing together powders. Utility model. The innovation concerns a mechanism for the filling of a press for squeezing together powders in stencils, which are stored into a horizontal turning table. For German Patent No. DE4025487, see Abstract listed on PTO Form 1449.

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP295DIV/DRC. This form is submitted in triplicate.

Respectfully submitted,

  
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Attorney for Applicants

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DATED: June 3, 2004

U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

**Examiner  
Signature**

Date  
Considered



Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/782,551
Filing Date	02/19/2004
First Named Inventor	Harry S. Sowden
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	MCP-0295DIV

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		599,865		Richards	1/1898	
		2,307,371		Hileman	5/43	
		2,415,997		Ekdred	2/47	
		3,300,083		Jensen et al.	1/67	
		3,563,170		Cvacho et al.	2/71	
		3,567,043		Sirvet et al.	3/71	
		3,656,518		Aronson	4/72	
		3,726,822		DeTroyer et al.	4/73	
		3,804,570		Hoschele et al.	4/74	
		3,832,252		Higuchi et al.	8/74	
		4,139,589		Beringer et al.	2/79	
		4,273,793		Fariel et al.	6/81	
		4,292,017		Doepel	9/81	
		4,371,516		Gregory et al.	2/83	
		4,392,493		Niemeijer	7/83	
		4,413,709	A	Shinichiro	11/83	
		4,473,526		Buhler et al.	9/84	
		4,518,335		Pujari	5/85	
		4,544,345		Buhler et al.	10/85	
		4,569,650		Kramer	2/86	
		4,781,714		Eckenhoff et al.	11/88	
		4,813,818		Sanzone	3/89	
		4,820,524		Berta	4/89	
		4,851,226		Julian et al.	7/89	
		4,965,027		Takahashi	10/90	
		5,059,112		Wieser	10/91	
		5,073,379	A	Bleckmann	12/91	
		5,075,114		Roche	12/91	
		5,089,270		Hampton et al.	2/92	
		5,146,730		Sadek et al.	9/92	
		5,200,191		Steele et al.	4/93	
		5,213,738		Hampton et al.	5/93	
		5,228,916		Berta	7/93	

Substitute for form 1449/APTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Application Number	10/782,551
Filing Date	02/19/2004
First Named Inventor	Harry S. Sowden
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	MCP-0295DIV

	5,229,164		Pins et al.	7/93	
	5,415,868		Smith et al.	5/95	
	5,421,447		Ruth et al.	6/95	
	5,436,026		Berta	7/95	
	5,456,563		Halbo, Hansjorg	10/95	
	5,459,983		Sadek et al.	10/95	
	5,464,631		Hoover et al.	11/95	
	5,489,436		Hoy et al.	2/96	
	5,511,381		Sauter	4/96	
	5,538,125		Berta	7/96	
	5,609,010		Sauter	3/97	
	5,679,406		Berta	10/97	
	5,782,337		Langland, George Raymond	7/98	
	5,795,588		Sauter	8/98	
	5,824,338		Jacobs et al.	10/98	
	5,830,501		Dong et al.	11/98	
	5,830,502		Dong et al.	11/98	
	5,834,035		Osada et al.	11/98	
	5,837,301		Arnott et al.	11/98	
	5,871,781		Myers et al.	2/99	
	5,942,034		Brehant et al.	8/99	
	5,997,905		McTeigue et al.	12/99	
	6,001,391		Zeidler et al.	12/99	
	6,117,479		Hogan et al.	9/00	
	6,149,943		McTeigue et al.	11/00	
	6,350,398	B1	Breitenbach et al.	2/02	
	6,405,853		Cook et al.	6/02	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

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Sheet 3 of 3

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## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		WO	9407470		Pfizer, Inc.	04/14/1994		
		WO	9902136		Greither (English abstract attached)	01/21/1999		
		WO	03/020246	A1	SmithKline Beecham PLC	03/13/2003		
		GB	1 227 837	A	Bliss Company	04/07/1971		
		GB	2 182 559	A	Alza Corporation (equivalent to FR 2 604 904)	05/20/1987		
		DE	40 25 487	A	Korsch Maschfab	02/13/1992		x
		DE	75 35 875	U	Ateliers De Construction Ed. Courtoy (see International Search Report)	03/11/1976		
		NL	8602556		Alza Corporation	10/10/1986		x
		FR	2 604 904		Alza Corporation (English abstract attached; equivalent to GB 2 182 559)	10/13/1986		
		EP	0 864 324	B1	BASF Aktiengesellschaft (English abstract attached)	03/12/1997		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Catellani et al., Int. J. Pharmaceutics, 88 (1992) 285-291, "Centrifugal die filling system in a new rotary tablet machine."	
		Cuff & Rauf, Pharm Tech, June 1998, 96-106, "A Preliminary Evaluation of Injection Molding as a Technology to Produce Tablets."	
		Lachman, Leon et al., "Chapter II - Tablets", The Theory and Practice of Industrial Pharmacy (1986), pp. 283-345	

Examiner Signature	Date Considered
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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